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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/603,819	06/26/2003	Thomas Nilsson	239639US8	2765

22850 7590 01/12/2006

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ART UNIT	**PAPER NUMBER**
1616	

DATE MAILED: 01/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/603,819	NILSSON ET AL.	
	Examiner	Art Unit	
	James H. Alstrum-Acevedo	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *June 26, 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20* is/are rejected.

7)☒ Claim(s) *18* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *12/17/03, 2/10/04*, 4/13/04, 11/5/04
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-20 are pending.

Specification

Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally **limited to a single paragraph on a separate sheet within the range of 50 to 150 words**. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

The abstract of the disclosure is objected to because it consists of two paragraphs and 201 words. Correction is required. See MPEP § 608.01(b).

The incorporation of essential material in the specification by reference to an unpublished U.S. application, foreign application or patent, or to a publication is improper. Applicant is required to amend the disclosure to include the material incorporated by reference, if the material is relied upon to overcome any objection, rejection, or other requirement imposed by the Office. The amendment must be accompanied by a statement executed by the applicant, or a practitioner representing the applicant, stating that the material being inserted is the material previously incorporated by reference and that the amendment contains no new matter. 37 CFR 1.57(f).

The disclosure is objected to because of the following informalities: the title of the disclosure on page 1 is missing the letter "o" in the word "administration."

Appropriate correction is required.

Claim 18 is objected to because of the following informalities: the word "therapeutical" should read "therapeutic." Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 1, 2, 5-8, 12-15, and 19-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "prolonged delivery" in claim 11is a relative term, which renders the claim indefinite. The term " prolonged delivery " is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. A person of ordinary skill in the art would not be able to accurately determine what amount of time (0.1 s, 1s, 10 s, 60 minutes, etc.) Applicant intended by the term "prolonged delivery."

The term "high" in claims 1, 5, 6, 11, 14, 15, and 19-20 is a relative term, which renders the claim indefinite. The term "high" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. A person of ordinary skill in the art would not be able to accurately determine what Applicant intended by the terms "high degree," "high percentage," and "high proportion."

The term "large proportion" in claim 11is a relative term, which renders the claim indefinite. The term "large proportion" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. A person of ordinary skill in the art would not be able to accurately determine what Applicant intended by the terms "large proportion."

The term "pure" in claims 7, 8, 12, and 13 is indefinite, because it connotes the lack of any impurities, however, it is well known to skilled artisans that absolute purity is impossible (See, for example, "General Remarks" in *Purification of Laboratory Chemicals, 4th ed.*, W. L. F. Amarego and D. D. Perrin, Eds. Elsevier, 1996, p 1). Therefore, a person of ordinary skill in the art would be unable to ascertain what degree of purity is intended by Applicant's use of the word "pure."

Claim 18 is confusing because it is unclear what the Applicant intends by the limitation "socially beneficial," regarding the therapeutic effect of the inhaled medicinal dose. A person of ordinary skill would not be able to ascertain whether the Applicant intends this phrase to suggest that the host user would increase their circle of friends and acquaintances by use of the claimed composition or whether some other meaning was intended. This phrase is not defined or explained further in the specification.

The remaining claims are rejected as being dependent upon a rejected claim.

Claims 5, 6, 14, 15, and 19-20 rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: the procedure of the Air-razor method.

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3, 5, 7, 8, 11, 12, and 18-20 rejected under 35 U.S.C. 102(b) as being anticipated by Haikarainen et al. (WO 00/64519).

Claims 11, 12, and 18-20 of the instant application are composition claims and therefore all limitations associated with preparative steps, any intended uses of said compositions, or steps associated in the using of the compositions are given no weight.

Haikarainen discloses a device for dispensing of a **powdered drug preparation by inhalation**, wherein the device comprises two or more powder containers for different drug powders, which can be inhaled as a combined medication (page 1, lines 4-9). This device is inherently a dry powder inhaler, because it dispenses powdered drug preparations by inhalation.

Haikarainen discloses that in the treatment of respiratory disorders it is often beneficial to administer a combination of drugs (e.g. a bronchodilator and an anti-inflammatory drug) to a patient (page 2, lines 1-3).

Haikarainen discloses that the active ingredients are contained in separate containers, from which the doses are **metered**, **brought to the air channel, and inhaled**. Furthermore, the inhaler can deliver **deaggregated medicament powder** from two or more dosing recesses simultaneously without the use of pressurized air, even if used by a patient having reduced inhalation capacity. The inhaled air stream is conducted via two separate aerosolization channels – one for each medicament- whereby the medicaments are mixed not earlier than the in the air channel or in the respiratory tract of the patient during inhalation (page 2, lines 23-38).

Haikarainen discloses a method for inhaling a dose of a first and second powdered medicaments comprising (a) providing an inhaler with an air flow path and a supply of the 1st and 2nd medicaments; (b) metering a dose of the 1st and 2nd powdered medicaments from the medicament supplies; (c) bringing the metered dose of the 1st and 2nd medicaments into the air flow path of the inhaler; (d) inhaling the metered dose of the 1st and 2nd powdered medicaments through the inhaler.

Claims 11-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Davies et al. (US 2002/005344 A1).

Claims 11-20 of the instant application are composition claims and therefore all limitations associated with preparative steps, any intended uses of said compositions, or steps associated in the using of the compositions are given no weight.

Davies discloses an **inhalation device** for use with a medicament pack in which at least one container for **medicament in powder form** is defined between two sheets peelably secured to one another, wherein said container may be opened, and through which a **user can inhale medicament in powder form** from the opened container (abstract). Davies' device is inherently a dry powder inhaler, based upon its description as an inhalation device for the delivery of medicament in powder form.

Davies discloses that the strip 1 comprises a base sheet 3 in which **blisters** are formed to define the pockets 2, and a lid sheet 4 which is **hermetically sealed** to the base sheet 3 except in the region of the blisters, such a manner that the lid sheet and the base sheet can be **peeled apart**. The sheets are sealed to one another over their whole width except for leading end portions thereof where they are preferably not sealed to one another at all [0041]. The medicament

contained within the strip of Davies' invention is inherently separately sealed (see part 203 in Fig. 9).

Davies discloses that the medicament dispenser of the invention is suitable to dispensing medicament, particularly for the **treatment of respiratory disorders** (e.g. asthma and chronic obstructive pulmonary disease (COPD)) [0091].

Davies identifies appropriate medicaments for use in his inhalation device, including **fluticasone propionate (an antihistamine) and formoterol fumarate (a bronchodilator)** [0093].

Davies states that it will be clear to a person skilled in the art that, where appropriate, the medicaments may be used in the form of **salts**, or as **esters** or as **solvates** to optimize the activity and/or stability of the medicament [0093].

Davies discloses that the medicaments **can also be delivered in combinations [0094].**

Davies discloses that inhalation devices are known for use with **blister packs** in which medicament is held in powder form in the blisters thereof [0003].

Davies discloses in Figs.1, 2, 3a to 3c, and 9 an inhalation device mounted with a flexible **strip 1, defining a plurality of pockets 2, each of which contains a dose of medicament which can be inhaled, in the form of powder** (i.e. a blister pack) [0041]. It is apparent upon visual inspection that part 203 depicted in Fig. 9 in Davies' device is a blister pack.

Davies discloses that when the user inhales through the mouthpiece 20 the flow of air, which this produces, entrains powder from the opened pocket, **so that the user inhales the powder** [0050].

Davies discloses that the directional airflow produced by the user's inhalation produces a swirling of airflow, which helps to distribute the powder effectively within the airflow, reducing deposition of the powder in the mouthpiece, and **helping to break up any aggregates of powder**, which may be present in the **blister** [0053].

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 11-20 are rejected under 35 U.S.C. 102(e) as being anticipated by Clarke et al. (US 2002/0103260).

Claims 11-20 of the instant application are composition claims and therefore all limitations associated with method steps and any intended uses of said compositions are given no weight.

Clarke discloses pharmaceutical compositions comprising (A) **formoterol or pharmaceutically acceptable salts and solvates thereof** and (B) **fluticasone propionate**, suitable for use in the **treatment of inflammatory or obstructive airways diseases** (abstract).

Clarke discloses that a significant unexpected, particularly synergistic therapeutic effect in the treatment of inflammatory or obstructive airways diseases has been obtained by using compositions comprising formoterol, or a salt or solvate thereof, and fluticasone propionate. These compositions induce an anti-inflammatory effect which is significantly greater than that induced by either **active** alone [0003].

Clarke discloses that pharmaceutically acceptable salts of formoterol include salts of inorganic and organic acids, include **salts of fumaric acid** (i.e. formoterol fumarate)[0009] and [0010].

Clarke discloses that the actives may be in the form of an **inhalable dry powder**, may contain a **pharmaceutically acceptable carrier** (e.g. lactose), in dosage units of the carrier and both actives in amounts of powder in each capsule from 5 mg to 50 mg [0012].

The active components (A) and (B) preferably have an average particle diameter of up to 1 to 5 microns [0013]. The pharmaceutical compositions may be administered using an **inhalation device** suitable for the inhalable form, such devices being well known in the art [0014], wherein, for example, the device is adapted to **deliver dry powder from a capsule of blister containing a dosage unit of dry powder** or a **multidose dry powder inhalation device** adapted to deliver, for example **5-25 mg of dry powder per actuation** [0015].

Clarke discloses that suitable daily doses of formoterol fumarate dihydrate for inhalation may be from **1 to 72 micrograms** and suitable daily doses of fluticasone for inhalation may be from **25 to 3,000 micrograms** [0017].

Clarke discloses that treatment of inflammatory or obstructive airways diseases may be symptomatic or prophylactic [0020], as well as conditions to which his disclosed treatment is applicable [0022].

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 2, 4, 6, and 9-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Davies et al. (US 2002/005344 A1).

The teachings of Davies have been set forth above.

It would have been obvious to a person of ordinary skill in the art at the time of the instant invention that Davies implicitly teaches a method of administering metered dry powder characterized by the steps of forming a dose bed as a blister pack and providing each separate deposit with a separate seal to prevent interaction between the deposited medicaments, because

Davies' device's strip is a blister pack in which the doses are hermetically sealed and Davies teaches his device is suitable for dispensing medication via inhalation for the treatment of respiratory diseases. It would have been obvious to a skilled artisan in the art at the time of the instant application upon visual inspection of Davies' Fig. 9 that that the separate medicament deposits displayed therein were separately sealed. It would have been obvious to a person of ordinary skill in the art at the time of the instant application that the teachings of Davies encompass an inhalation device for prolonged delivery. The term "prolonged delivery," although undefined in the specification and indefinite, is interpreted as referring to the duration of a subject's inhalation, per the last phrase of claim 2: "to a user inhaling once through the DPI." Furthermore, the term continuous is given little weight, since the duration of the inhaler's use is limited by the duration of the user's inhalation, and therefore cannot be continuous. It would have been apparent to a skilled artisan that combined dosages of formoterol and fluticasone could be administered from an inhalation device simultaneously, sequentially, or in combination thereof, because Davies teaches that these drugs may be used in combination. Furthermore, it would be obvious that sequential blister packs could separately contain each component of a composition, to provide a separate and sequential administration. Due to the similarities between the compositions and methods taught explicitly or implicitly by Davies, a skilled artisan would have had a reasonable expectation of successfully using these teachings to obtain the instant invention.

Claims 2, 4, and 6 are rejected under 35 U.S.C. 103(a) as being obvious over Nilsson et al. (U.S. Patent No. 6,422,236).

The applied reference has a common assignee (Microdrug AG) and common inventors (Thomas Nilsson and Mattias Myrman) with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). This rejection might also be overcome by showing that the reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(l)(1) and § 706.02(l)(2).

Nilsson teaches a **continuous dry powder inhaler** (cDPI) arrangement is disclosed, the provided with electrostatically **dosed medical powder** onto an exchangeable dosing member for respiratory administration of medicaments **into the deep or upper lung airways**. The medical drugs contained within the cDPI are prepared for continuous dosing in sequentially sealed doses, which are sealed. The cDPI contains a braking arrangement, which can be adjusted so that the continuous delivery of the powder will be **prolonged to an order of 1 to 2 seconds** (abstract).

It would have been obvious to a person of ordinary skill in the art at the time of the instant invention that Nilsson implicitly teaches a method of administration, because his device is

intended fro the respiratory administration of medicaments into the lungs and his device may be adjusted to prolong the continuous delivery of powdered medicament.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); In re Van Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-8, 11-15, and 18-20 of the instant application are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over all the claims of copending Application No. 10/603,818 (copending '818). Although the conflicting claims are not identical, they are not patentably distinct from each other because are overlapping in scope and/or are obvious over one another. The claims of copending '818 either require general classes of medicaments (i.e. bronchodilators and anti-inflammatories) or require the election of medicaments from large groups, including formoterol and fluticasone. The

instant application does not specify classes of medicaments or identify specific drugs, however the term "medicament" encompasses all drug classes and therefore all drug types.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-4, 7-13, and 16-18 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-6 and 10-11 of copending Application No. 10/703,505 (copending '505). Although the conflicting claims are not identical, they are not patentably distinct from each other because are overlapping in scope and/or are obvious over one another. The claims of copending '505 do not name a specific medicament and therefore encompass this limitation in the above-cited claims of the instant application. Both claim sets, also have limitations requiring that the medicaments cannot "detrimentally mix."

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1, 2, 7, 8, 11-15, and 18-20 of the instant application are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 23-25 of copending Application No. 10/728,986 (copending '986). Although the conflicting claims are not identical, they are not patentably distinct from each other because are overlapping in scope and/or are obvious over one another. The claims of copending '986 comprise tiotropium and at least one other active pharmaceutical agent chosen from several classes of drugs. The difference between claims 1, 2, 7, 8, 11-15, and 18-20 of the instant

application and claims 23-25 of copending '986 is that the compositions of the instant application are not drawn to specific drug classes. It is noted that the term "medicament" encompasses all drug classes, and therefore all drugs.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-4, 7, 8, 11-15, and 18-20 of the instant application are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-23 of copending Application No. 10/870,907 (copending '907) in view of Akehurst (U.S. Patent No. 6,303,103) (USPN '103). Although the conflicting claims are not identical, they are not patentably distinct from each other because are overlapping in scope and/or are obvious over one another. The claims of copending '907 involve compositions containing two to three actives (A, B, and/or C) corresponding to a beta2-agonist (A), an anticholinergic (B), and an anti-inflammatory corticosteroid (C). The difference between claims 1-4, 7, 8, 11-15, and 18-20 of the instant application and claims 1-23 of copending '907 is that the compositions of the instant application are not drawn to specific active agents. It is noted that the term "medicament" encompasses all drug classes, and therefore all drugs.

The Examiner contends that the cited claims of copending '907 are obvious over those of the instant application, because USPN '103 teaches that it is preferable that compositions contain medicant particles with particle sizes within the range of 1-10 microns (col. 2, lines 27-31).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-8, 11-15, and 18-20 of the instant application are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over all the claims of copending Application No. 10/870,909 (copending '909). Although the conflicting claims are not identical, they are not patentably distinct from each other because are overlapping in scope and/or are obvious over one another. The claims of copending '909 require compositions containing medicaments A (formoterol) and B (budesonide). It is noted that the term "medicament" encompasses all drug classes, and therefore all drugs.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-8, 11-15, and 18-20 of the instant application are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over all the claims of copending Application No. 10/870,945 (copending '945). Although the conflicting claims are not identical, they are not patentably distinct from each other because are overlapping in scope and/or are obvious over one another. The claims of copending '945 involve compositions containing two actives (A and B) corresponding to formoterol (A) and an anticholinergic (B). The difference between claims 1-8, 11-15, and 18-20 of the instant application and the claims of copending '945 is that the compositions of the instant application are not drawn to specific active agents. It is noted that the term "medicament" encompasses all drug classes, and therefore all drugs.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 11-15 and 18-20 of the instant application are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 2, 10, and 15-17 of copending Application No. 10/921,192 (copending '192) in view of Akehurst (USPN '103). Although the conflicting claims are not identical, they are not patentably distinct from each other because are overlapping in scope and/or are obvious over one another. The difference between the aforementioned claims of copending '192 and claims 11-15 and 18-20 of the instant application is that the claims of copending '192 (1) the compositions comprise tiotropium and at least one second active selected from several classes of drugs, including inhalable steroids, beta-agonists, and anti-histamines.

The Examiner contends that the cited claims of copending '192 are obvious over those of the instant application, because the term "medicament" used in the instant application encompasses all drugs, including tiotropium. Furthermore, the phrase "at least one drug" used in the claims of copending '192 encompasses the phrase "at least two medicaments" used in the instant application. The Examiner further contends that claims 11-15 and 18-20 of the instant application are obvious over claims 1, 2, 10, and 15-17 of copending '192, because USPN '103 teaches that it is preferable that compositions contain medicant particles with sizes within the range of 1-10 microns (col. 2, lines 27-31). Diameter is a measure of the size of a particle, therefore, it would have been obvious to a person of ordinary skill in the art that mass median diameter is affected by particle size. Optimization of particle size, therefore results in optimization of mass median particle diameter.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 11-16 and 18-20 of the instant application are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-6, 10, 13, and 14 of copending Application No. 11/085,523 (copending '523) in view of Akehurst (USPN '103). Although the conflicting claims are not identical, they are not patentably distinct from each other because are overlapping in scope and/or are obvious over one another. The difference between the aforementioned claims of copending '523 and the claims 11-16 and 18-20 of the instant application is that the claims of copending '523 (1) have limitations regarding aerodynamic diameter and dosage amounts. The amount of a specific ingredient in a composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ. It would have been customary for an artisan of ordinary skill to determine the optimal amount of each ingredient needed to achieve the desired results. Thus, absent some demonstration of unexpected results from the claimed parameters, the optimization of ingredient amounts would have been obvious at the time of applicant's invention.

The Examiner contends that claims 11-16 and 18-20 of the instant application are obvious over claims 1-6, 10, 13, and 14 of copending '523, because USPN '103 teaches that it is preferable that compositions contain medicant particles with sizes within the range of 1-10 microns (col. 2, lines 27-31).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusions

The specification, abstract, and claim 18 are objected. Claims 1-20 are rejected. No Claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James H. Alstrum-Acevedo whose telephone number is (571) 272-5548. The examiner can normally be reached on M-F, 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni (Paddy) Padmanabhan can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

James H. Alstrum-Acevedo, Ph.D.
Examiner

SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER